Docket No.: 20747/240 (ARDCK/P32478US)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	;	Ong et al.	) Examiner:	
Serial No.	:	10/525,266 based on PCT/GB2003/003669	)	Unknown
Int'l Filing Date	:	August 21, 2003	) ) )	Art Unit: 1645
Cnfrm. No.	÷	4952	)	
For	:	GROWTH HORMONE-RELEASING PEPTIDES IN THE TREATMENT OF PREVENTION OF ATHEROSCLEROSIS AND HYPERCHOLESTEROLEMIA	) ) ) )	
			,	

## REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Dear Sir:

Applicants hereby request a corrected filing receipt for the above-identified application. On the enclosed copy of the official filing receipt, the filing date of the domestic priority data is incorrect. The domestic priority data should be "This application is a 371 of PCT/GB03/03669 08/21/2003 which claims benefit of 60/467,890 05/05/2003" (correction underlined). A replacement Transmittal Letter to the United States Designated/Elected Office, and copy of the cover page of the PCT published application (WO 2004/017986 A1) are enclosed.

Since Applicants are responsible for this error, the Commissioner is hereby authorized to charge any necessary fees to Deposit Account No. 14-1138. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

Dated: August 24, 2006

Edwin V. Merkel Registration No. 40,087

Nixon Peabody LLP Clinton Square, P.O. Box 31051 Rochester, New York 14603-1051 Telephone: (585) 263-1128

Facsimile: (585) 263-1600



## United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FOR 1550 Alexandria, Vignaia 22313-1450 www.copto.gov

FILING OR 371 APPL NO ART UNIT FIL FEE REC'D ATTY. DOCKET NO DRAWINGS TOT CLMS IND CLMS (c) DATE 10/525,266 04/25/2006 1645 2030 20747/240 10 19 8

**CONFIRMATION NO. 4952** 

Edwin V Merkel Nixon Peabody Clinton Square P O Box 31051 Rochester, NY 14603

Nixon Peabody LLP

JUL 3 1 2006

**FILING RECEIPT** OC000000019648996\*

Date Mailed: 07/19/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon, If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

#### Applicant(s)

Huy Ong, Ville Mont-Royal, CANADA; Sylvie Marleau, Rosemere, CANADA; Andre Tremblay, Laval-des-Rapides, CANADA;

#### Power of Attorney:

Edwin Merkel--40087

#### Domestic Priority data as claimed by applicant

This application is a 371 of PCT/GB03/03669 08/23/2003 Should be 06/21/2003 which claims benefit of 60/467,890 05/05/2003

#### Foreign Applications

CANADA 2399548 08/23/2002

If Required, Foreign Filing License Granted: 07/17/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/525,266

Projected Publication Date: 10/26/2006

Non-Publication Request: No

Early Publication Request: No

Title

Growth hormone-releasing peptides in the treatment of prevention of atherosclerosis and hypercholesterolemia

**Preliminary Class** 

424

## PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

# LICENSE FOR FOREIGN FILING UNDER Title 35, United States Code, Section 184 Title 37, Code of Federal Regulations, 5.11 & 5.15

#### **GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted

under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

#### NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

PTO-1390 (Rev. 02-2005)
Approved for use through 3/31/2007. OM8 0651-0621
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

	TRANSMITTAL LETTER T		ATTORNEY'S DOCKET NUMBER					
_	DESIGNATED/ELECTED	20747/240 U.S. APPLICATION NO. (If known, see 37 CFR 1.5)						
C	ONCERNING A SUBMISSI	ON UNDER 35 U.S.C. 371						
INTER	PCT/GB03/003669	international filing date 21 August 2003 (21.08.2003)	PRIORITY DATE CLAIMED 23 August 2002 (23.08.2002)					
TITLE			THE TREATMENT OF PREVENTION OF					
ATHE	ROSCLEROSIS AND HYPERO	CHOLESTEROLEMIA						
41-1-1-1	cant(s) for doleolos ONG, Huy	; MARLEAU, Sylvie and TREM	BLAY, Andre					
Applic	ant herewith submits to the United S	tates Designated/Elected Office (DO/EO	/US) the following items and other information:					
1. X	This is a FIRST submission of items of	oncerning a submission under 35 U.S.C. 371.						
. <u> </u>	This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.							
3. X This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.								
. X	The US has been elected (Article 31).							
X	A copy of the International Application as filed (35 U.S.C. 371(c)(2))							
a. is attached hereto (required only if not communicated by the International Bureau).								
	b. X has been communicated by	the International Bureau.						
	c is not required, as the appli	cation was filed in the United States Receiving	g Office (RO/US).					
		e International Application as filed (35 U.S.C.	371(c)(2)).					
	a. Lis attached hereto.							
X		ted under 35 U.S.C. 154(d)(4).						
	<del>[ ]</del>	mational Application under PCT Article 19 (35						
		ed only if not communicated by the Internation	nal Bureau).					
	b. have been communicated I							
	াতা	ver, the time limit for making such amendmen	its has NOT expired.					
$\Box$								
	An english language translation of the An oath or declaration of the inventor(s	amendments to the claims under PCT Article	9 19 (35 U.S.C. 371(c)(3)).					
		annexes of the International Preliminary Exam	nination Report under PCT					
	Article 36 (35 U.S.C. 371(c)(5)).							
	11 to 20 below concern document(s) of	or information included:						
X	An Information Disclosure Statement ur	nder 37 CFR 1.97 and 1.98.						
	An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.							
A preliminary amendment.								
	An Application Data Sheet under 37 CF	R 1.76.						
니 <b>그</b>	A substitute specification.							
A power of attorney and/or change of address letter.								
7		ce listing in accordance with PCT Rule 13ter.;	2 and 37 CFR 1.821- 1.825.					
ر ا	A second copy of the published Internation	onal Application under 35 U.S.C. 154(d)(4).						
		anslation of the international application unde						
$\mathbf{X}$ $\mathbf{I}$	Other items or information: Unsigned Con	abined Declaration & Power of Attorney; Copy	y of Intnl Prelim. Exam. Report w/Amended Sheets					

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450, DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mall Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Page 1 of 2

## (19) World Intellectual Property Organization

International Bureau



## 

(43) International Publication Date 4 March 2004 (04.03.2004)

PCT

### (10) International Publication Number WO 2004/017986 A1

(51) International Patent Classification<sup>7</sup>: A61K 38/08. 38/25, A61P 9/10

(21) International Application Number:

PCT/GB2003/003669

- (22) International Filing Date: 21 August 2003 (21.08.2003)
- (25) Filing Language:

English

(26) Publication Language:

English

- (30) Priority Data: 2,399,548 23 August 2002 (23.08.2002) CA 5 May 2003 (05.05.2003) 60/467,890 US
- (71) Applicant (for all designated States except US, UZ): UNI-VERSITY OF MONTREAL [CA/CA]; P.O.Box 6128, Station A, Montreal, Quebec, H3C 3J7 (CA).
- (71) Applicant (for UZ only): MCNEENEY, Stephen, Phillip [GB/GB]; Park View House, 58 The Ropewalk, Nottingham NG1 5DD (GB).
- (72) Inventors: and
- (75) Inventors/Applicants (for US only): ONG, Huy

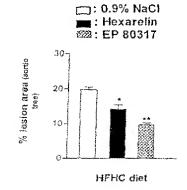
[CA/CA]; 2220 Chemin Cambridge, Ville Mont-Royal, Quebec, H3R 2YE (CA). MARLEAU, Sylvie [CA/CA]; 238 Rose-Alma, Rosemère, Quebec, J7A 3B8 (CA). TREMBLAY, André [CA/CA]; 305 De Noirmoutier, Laval-des-Rapides, Quebec, H7N 5L1 (CA).

- (74) Agent: MCNEENEY, Stephen; Eric Potter Clarkson, Park View House, 58 The Ropewalk, Nottingham NG1 5DD (GB).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM). European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, TE, TT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: GROWTH HORMONE-RELEASING PEPTIDES IN THE TREATMENT OF PREVENTION OF ATHEROSCLERO-SIS AND HYPERCHOLESTEROLEMIA

AboE-null mice, 12 weeks treatment with GHRPs



",  $\rho$  < 0.01 and "",  $\rho$  < 0.001 compared with 0.9% NaCl; #,  $\rho$  < 0.05 compared with HEX

(57) Abstract: According to the invention there is provided a method of treatment or prophylaxis of atherosclerosis, hypercholesterolemia or a cardiovascular disease associated with atherosclerosis, which method comprises administration of one or more Growth Hormone Releasing Peptides (GHRPs) to a patient in need of such treatment or prophylaxis. There are also provided methods of reducing blood plasma cholesterol levels, as well as methods of modulating the expression of the scavenger receptor CD36 and genes involved in cellular cholesterol efflux.